Docket: 55017-8377

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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In re application of:
Maisey, et al.

Serial No.: 09/943,647

Filed: August 30, 2001

For: TEST DEVICE

Examiner: ALEXANDER, Lyle

Group Art Unit: 1743

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APPEAL BRIEF OF THE APPLICANT UNDER 37 C.F.R. § 1.192

COMES NOW Applicant and submit its appeal brief and argument to the U.S. Patent Office Board of Patent Appeals and Interferences under 37 C.F.R. §1.192 of the Examiner's Final Rejection of Claims 1-27 of U.S. Patent Application Serial No.

09/943,647, filed August 30, 2001 and titled TEST DEVICE. This Brief of the Applicants is filed in triplicate.

(1) Real Party In Interest

This Application was assigned to Hypoguard Limited, the Assignments being recorded on January 3, 2003 at Reel No. 013628 and Frame No. 0091. Hypoguard Limited is the real party in interest, having a 100% interest in the subject application.

(2) Related Appeals and Interferences

Applicants' attorney is not aware of any related appeals or interferences.

(3) Status of Claims

Claims 1-27 are pending in the application. This is an appeal from the final rejection of Claims 1-27 made in the Office Action of Paper No. 11, mailed November 13, 2003. The Claims on appeal are Claims 1-27 and are set forth in full in the Appendix of Claims on Appeal attached hereto and incorporated herein.

(4) Status of Amendments

Amendment and Response To The Office Action of Paper No. 9 was filed on February August 29, 2003 and entered. In Amendment and Response To The Office Action of Paper No. 9, claims1 and 21 were amended to correct typographical errors.

The Examiner subsequently rejected claims 1-27 in the Office Action of Paper No. 11, and made the rejection Final. No further amendments were made to the Claims.

(5) Summary of the Invention

As specified in independent claim 1 on appeal, the invention is directed to a test device for testing of analyte concentration in a fluid, such as blood glucose or other analytes in bodily fluids to be applied thereto (page 1, lines 7-10). The test device comprises a plurality of sensors 16 arranged in a stack (page 2, line 34; drawing figures 1-7). Each of the sensors 16 carries reagent means for producing an electrical signal in response to the concentration of analyte in an applied fluid, and each has a plurality of electrode tracks 50 for transmitting said electrical signal (page 2 , line 34, to page 3, line 2). The test device further comprises a housing 2 having an opening 14 therein and containing the said stack of sensors 16 (page 3, lines 3-4). Still further, the test device comprises electrical contacts mounted in relation to the housing 2 for engaging with electrode tracks 50 on a sensor 16 at an engagement location and a meter connected to the said electrical contacts (page 3, lines 5-7). The meter has electronics means for producing a signal output which is dependent on the electrical signal from a sensor when the sensor is engaged with the said contacts (page 3, lines 9-11). Additionally, the test device comprises a transport member 4 rotatably mounted in the opening 14 of the housing 2 (page 3, lines 12-13). The transport member 4 has an axis of rotation which spans the opening and has an outer surface which is provided with a recessed region 12 adapted to receive a single sensor 16 from the stack (page 3, lines 13-16).

Still further, the test device comprises spring means 24 within the housing 2 which urge the stack of sensors 16 towards the transport member 4 and which urge a single sensor into the recess 12 when the recess is suitably aligned adjacent to the stack (page 3, lines 17-20). The test device further comprises sealing means 20 for making a moisture tight seal between the transport member 4 and the stack 16 when the transport member is in a specified rotational position (page 3 lines 21-23). Rotation of the transport member 4 with a sensor 16 in the recessed region 12 transports the sensor to the engagement location or to a position where the sensor can be moved to the engagement location, whereby electrode tracks 50 of the sensor can engage with the said electrical contacts (page 3, lines 25-30).

As specified in dependent claim 2, which depends from claim 1, the sensors 16 of the test device are stacked in a magazine 18 within the housing 2 (page 11, lines 16-17). The magazine 18 has a single opening which faces the transport member 4.

As specified in dependent claim 3, which depends from claim 2, a first end of the sealing means 20 of the test device forms a seal around the magazine 18 and a second end of the sealing means locates in a groove 26 in the transport member 4 to form a seal therewith when the recessed region 12 of the transport member is in register with the stack of sensors 16 (page 12, lines 2-8).

As specified in dependent claim 4, which depends from claim 3, the sealing means 20 of the test device comprises a retractable sleeve which sealingly engages in the groove 26 of the transport member 4 when in an extended configuration and which

does not form a seal with the transport member when in a retracted configuration (page 12, lines 2-14).

As specified in dependent claim 5, which depends from claim 1, the test device is provided with a pusher 28 to impart translational motion to a sensor 16 mounted in the recessed region 12 during and/or after rotation of the transport member 4 so as to bring the sensor to the engagement location (page 12, 28-32).

As specified in dependent claim 6, which depends from claim 5, the pusher 25 of the test device is mounted on the transport member 4 and a portion of the pusher is located in a helical track 30 in the housing 2 whereby rotation of the transport member imparts translational motion to the pusher (page 12, lines 28-32).

As specified in dependent claim 7, which depends from claim 1, the opening 14 is the only opening to the inside of the housing 2 (drawing figures 2a, 3a, and 4a). Moreover, the sealing means 20 comprises a seal which is secured in relation to an outer surface of the transport member 4 and which seals the opening of the housing 2 when the transport member is in a specified rotational position (page 12, lines 2-9).

As specified in dependent claim 8, which depends from claim 2, the sealing means 20 comprises a seal which is secured in relation to an outer surface of the transport member 4 and which seals the opening of the magazine 18 when the transport member is in a specified rotational position (page 12, lines 2-9).

As specified in dependent claim 9, which depends from claim 1, the opening 14 of the test device is the only opening to the inside of the housing 2 (drawing figures 14-19). Moreover, the sealing means 20 comprises a seal 66 provided on a door 52 which

is adapted to fit the opening so that the moisture tight seal is effected by closure of the door (page 14, lines 32-35). Additionally, the door 52 is operatively connected to the transport member 4 so that the door will be open when the transport member is in a first rotational position and closed when the transport member is in a second rotational position (page 15, lines 10-15).

As specified in dependent claim 10, which depends from claim 2, the sealing means 20 comprises a seal 66 provided on a door 52 which is adapted to fit the opening of the magazine so that the moisture tight seal is effected by closure of the door (page 14, lines 32-35). Additionally, the door 52 is operatively connected to the transport member 4 so that the door will be open when the transport member is in a first rotational position and closed when the transport member is in a second rotational position (page 15, lines 10-15).

As specified in dependent claim 11, which depends from claim 9, the door 52 of the test device is provided with one or more teeth 54 which restrain movement of the stack of sensors 16 against the force of the spring means 24 (page 15, lines 17-19).

As specified in dependent claim 12, which depends from claim 11, the transport member 4 is provided with at least one blade 62 which takes over the function of restraining the stack of sensors 16 when the door 52 is opened (page 15, lines 17-19).

As specified in dependent claim 13, which depends from claim 9, the door 52 of the test device is pivotally mounted in relation to the housing 2 (page 14, line 37, to page 15, line 2).

As specified in claim 14, which depends from claim 1, the transport member 4 is operationally connected to a return spring 38 which urges the transport member to adopt a specified rotational position at which the sealing means 20 can provide a moisture proof seal between the stack of sensors 16 and the transport member (page 16, lines 1-3).

As specified in dependent claim 15, which depends from claim 1, a portion of the sensor 16 to which a fluid sample is to be applied is not supported by the transport member 4 when in the engagement location (page 13, lines 18-20; drawing figures 8-13).

As specified in dependent claim 16, which depends from claim 1, the transport member 4 has an external profile which is substantially circular in cross section (page 11, lines 17-20).

As specified in independent claim 17, a test device for testing of analyte concentration in a fluid to be applied thereto comprises a housing 2, a transport member 4, and a spring means 24. The housing 2 contains a stack of test strips 16 and has an opening 14 therein (page 11, line 14-20). The transport member is rotatably mounted in the opening 14 of the housing 2 and has an axis of rotation which spans the opening (page 11, lines 16-20). The transport member 4 has a recessed region 12 adapted to receive a single test strip 16 (page 11, lines 20-27). The spring means 24 urge the stack 16 towards the transport member 4 (page 12, lines 9-14). Rotation of the transport member 4 with a test strip 16 in the recessed region 12 thereof brings the test strip to an engagement location at which it can be engaged with electrical contacts of a

meter and at which the test strip will be accessible to permit a user to apply a drop of fluid thereto (page 11, lines 20-29).

As specified in dependent claim 18, which depends from claim 17, the test device further includes sealing means 20 which make a moisture-proof seal between the transport member 4 and the stack 16 when the transport member is in a specified rotational position (page 12, lines 2-9).

As specified in dependent claim 19, which depends from claim 1, each sensor in the stack of sensors 16 comprises a base member 38 having a working area 40 to which the fluid is to be applied, containing the reagent means, and a non-working area 44 adjacent to the working area (figure 20; page 20, lines 7-27). The total thickness of the sensor 16 in at least a portion of the non-working area 44 is at least as great as the total thickness of the sensor in the working area 40 (page 20, lines 7-27).

As specified in dependent claim 20, which depends from claim 19, the total thickness of the sensor 16 in at least a part of the non-working area 44 is greater than the total thickness of the sensor in the working area 40 (page 20, lines 25-27).

As specified in independent claim 21, a test device for testing of analyte concentration in a fluid to be applied thereto comprises, among other things, a plurality of sensors arranged in a stack (page 11, lines 14-17). Each of the sensors 16 carries reagent means for producing an electrical signal in response to the concentration of analyte in an applied fluid, and each has a plurality of electrode tracks 50 for transmitting said electrical signal (page 2 , line 34, to page 3, line 2). The test device

further comprises a housing 2 having an opening therein 14 and containing the stack of sensors 16 (page 11, lines 14-17). Still further, the test device comprises electrical contacts mounted in relation to the housing 2 for engaging with electrode tracks 50 on a sensor 16 at an engagement location (page 3, lines 5-7). The test device also comprises a meter connected to the electrical contacts that has electronics means for producing a signal output which is dependent on the electrical signal from a sensor 16 when the sensor is engaged with the contacts (page 3, lines 9-11). Furthermore, the te4st device comprises a transport member 4 rotatably mounted in the opening 14 of the housing 2 (page 11, lines17-20). The transport member 4 has an outer surface which is provided with a recessed region 12 adapted to receive a single sensor from the stack of sensors 16 (page 11, lines 20-27). Still further, the test device comprises spring means 24 within the housing 2 which urge the stack of sensors 16 towards the transport member 4 in a direction substantially perpendicular to a plane containing the axis of rotation of the transport member, and which urge a single sensor into the said recess 12 when the recess is suitably aligned adjacent to the stack (page 12, lines 9-12). Additionally, the test device comprises sealing means 20 for making a moisture tight seal between the transport member 4 and the stack of sensors 16 when the transport member is in a specified rotational position (page 12, lines 2-9). Rotation of the transport member 4 with a sensor 16 in the recessed region 12 will transport the sensor to the engagement location or to a position where the sensor can be moved to the engagement location, whereby electrode tracks of the sensor can engage with the said electrical contacts (page 12, lines 24-35).

As specified in dependent claim 22, which depends from claim1, a test device includes load means 70 for applying a compressive load to a sensor 16 during at least a part of the time when the sensor is located in the recessed region 12 of the transport member 4 (page 16, lines 5-26).

As specified in dependent claim 23, which depends from claim 1, a test device comprises non-return means 78 which prevent or inhibit transport of a sensor 16 from the engagement location to the magazine and which prevent or inhibit reintroduction of an ejected used sensor to the engagement location (page 16, line 28, to page 17, line 8).

As specified in dependent claim 24, which depends from claim 23, the non-return means of the test device and the load means comprise a single resilient and flexible component 70 (page 16, line 5, to page 17, line 8; drawing figures 21-24).

As specified in dependent claim 25, which depends from claim 1, the test device comprises ratchet means associated with the stack of sensors which prevent or inhibit movement of the stack 16 in a direction opposite to that in which the spring means 24 urges the stack (page 17, lines 10-22; drawing figures 25 and 26).

As specified in independent claim 26, a test device for testing of analyte concentration in a fluid to be applied thereto comprises a housing 2, a transport member 4, and spring means 24 (page 11, line 14, to page 12 line 14). The housing 2 contains a stack of test strips 16 and has an opening 14 therein (page 11, lines 14-20). The transport member 4 is rotationally mounted in the opening 14 of the housing 2 and has a recessed region 12 adapted to receive a single test strip 16 (page 11, lines 17-27).

The spring means urge the stack 16 towards the transport member 4 (page 12, lines 9-14). Rotation of the transport member 4 with a test strip 16 in the recessed region 12 thereof will bring the said test strip to an engagement location at which it can be engaged with electrical contacts of a meter and at which the test strip will be accessible to permit a user to apply a drop of fluid thereto or to a position from which the sensor can be moved to the engagement location (page 12, lines 24-35). Additionally, load means 70 are provided between the transport member 4 and the housing 2 thereof, for applying a compressive load to a sensor 16 during at least a part of the time when the said sensor is located in the recessed region 12 of the transport member (page 16, lines 5-26).

As specified in dependent claim 27, which depends from claim 1, the test device is suitable for use in testing glucose concentration in blood (page 11, lines14-17).

It should be appreciated that the references to pages of the specification and drawing figures herein are exemplary of where support for the described invention can be found. However, support for the described invention is not necessarily limited to such specific references.

(6) Issues on Appeal

A. Whether the Examiner incorrectly concluded that claims 1-27 are anticipated by WO 94/10558 (hereinafter the '558 reference).

(7) Grouping of Claims

Claim 1, 17, 21, and 26 each stand alone as independently patentable claims with respect to the issues involved in this Appeal.

Claims 2, 15, 16, and 19, and 27 stand or fall with claim 1.

Claim 3 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claim 1 and, as explained below, is allowable for additional reasons.

Claim 4 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claims 1 and 3 and, as explained below, is allowable for additional reasons.

Claim 5 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claim 1 and, as explained below, is allowable for additional reasons.

Claim 6 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claims 1 and 5 and, as explained below, is allowable for additional reasons.

Claim 7 and 8 stand together with respect to the issues involved in this appeal; these claims are allowable for the same reasons as claim 1 and, as explained below, are allowable for additional reasons.

Claims 9, 10, and 13 stand together with respect to the issues involved in this appeal; these claims are allowable for the same reasons as claim 1 and, as explained below, are allowable for additional reasons.

Claim 11 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claims 1 and 9 and, as explained below, is allowable for additional reasons.

Claim 12 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claims 1, 9, and 11 and, as explained below, is allowable for additional reasons.

Claim 14 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claim 1 and, as explained below, is allowable for additional reasons.

Claim 18 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claim 17 and, as explained below, is allowable for additional reasons.

Claim 20 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claim 1 and, as explained below, is allowable for additional reasons.

Claim 22 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claim 1 and, as explained below, is allowable for additional reasons.

Claim 23 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claim 1 and, as explained below, is allowable for additional reasons.

Claim 24 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claims 1 and 23 and, as explained below, is allowable for additional reasons.

Claim 25 stands alone with respect to the issues involved in this appeal; this claim is allowable for the same reasons as claim 1 and, as explained below, is allowable for additional reasons.

(8) Arguments on Patentability

Legal precedent clearly establishes that "an anticipation rejection requires a showing that each limitation of the claim must be found in a single reference, practice, or device." *In re Donohue*, 226 USPQ 619, 621 (Fed. Cir. 1985). Furthermore, "[f]or a prior art reference to anticipate, every element of the claimed invention must be *identically* shown in a single reference." *In re Bond*, 15 USPQ 2d 1566, 1567-68 (Fed. Cir. 1990) (*emphasis added*). However, in rejecting claims 1-27, the Examiner has failed to address specific limitations of each claim, despite Applicant's previous attempt to point out such limitations for consideration. Such limitations are clearly not disclosed in the '558 reference.

Independent claim 1 is drawn to a test device for testing of analyte concentration in a fluid. Claim 1 requires, among other things, that the test device to comprise a housing having an opening therein and containing a stack of sensors. Furthermore, claim 1 requires the test device to comprise electrical contacts mounted in relation to the housing for engaging with electrode tracks on one of the sensors at an engagement

location. Additionally, claim 1 requires that the test device to comprise a transport member *rotatably* mounted in the opening of the housing. Moreover, claim 1 requires the transport member to have an *axis of rotation which spans the opening* and has an outer surface which is provided with *a recessed region* adapted to receive a single sensor from the stack. Still further, claim 1 requires that rotation of the transport member with a sensor in the recessed region transports the sensor to the engagement location or to a position where the sensor can be moved to the engagement location.

Applicant has submitted and hereby resubmits that the '558 reference fails to disclose, explicitly or inherently, a test device having transport member that is rotatably mounted in the opening of the housing and that has an axis of rotation which spans the opening. The Examiner has submitted that the claimed limitation of the transport member being rotatable is anticipated via the disclosure of the "daisy wheel" configuration in the '558 reference. (Office Action of Paper No. 11, dated November 13, 2003, third paragraph under the heading Response To Arguments; page 2, last sentence of fifth paragraph of the '558 reference). However, there is no disclosure in the '558 reference of such a rotatable daisy wheel member having any *recessed region* adapted to receive a single sensor from the stack, as is also required by claim 1. Additionally, the daisy wheel member is disclosed in the '558 reference as being an alternative embodiment of an "ejector" for displacing spent electrode elements from the test station. (page 2, fifth paragraph of the '558 reference) Thus, such a daisy wheel member would not transport any sensor to an engagement location or to a position where the sensor can be moved to the engagement location, as required by claim 1.

Moreover, the '558 reference makes no particular mention of the orientation of the axis of such a rotatable daisy wheel test member. In fact, in view of the configuration of the test device disclosed in the '558 reference, Applicant submits that a daisy wheel transport member would rotate about an axis that is perpendicular to the opening of the housing of the test device, and therefore the axis of rotation would not span or extend across the opening as required by claim 1. Thus the '558 reference can not possibly teach or even suggest a transport member having an axis of rotation that spans the opening of the housing.

Because the '558 reference fails to disclose or suggest the above-mentioned limitations of claim 1, the '558 reference does not anticipate claim 1. For these same reasons, claims 2-16, 19, 20, 22-25, and 27, being dependent upon claim 1, are therefore also not anticipated by the '558 reference.

Independent claim 17 requires a housing having an opening, and a transport member having an axis of rotation which spans the opening and which, when rotated, brings a test strip to an engagement location at which is can be engaged with electrical contacts of a meter. As mentioned above, the '558 reference discloses a device having an ejector which moves in a manner to separate a sensor from electrical contacts so as to eject it from the apparatus but fails to disclose or suggest any transport member, which is rotatable about an axis that spans an opening and fails to disclose any transport member that moves any test strip into engagement with electrical contacts.

Because the '558 reference fails to disclose or suggest the above-mentioned limitations of claim 17, the '558 reference does not anticipate claim 17. For these same

reasons, claim 18, being dependent upon claim 17, is therefore also not anticipated by the '558 reference.

Independent claim 21 requires a transport member that, when rotated, will transport a sensor to the engagement location or to a position where the sensor can be moved to the engagement location. Claim 21 also requires spring means within the housing which urges the stack of sensors towards the transport member in a direction substantially perpendicular to a plane containing the axis of rotation of the transport member. Again, the '558 reference discloses a device having an ejector which moves in a manner to separate a sensor from electrical contacts so as to eject it from the apparatus but fails to disclose or suggest any transport member, when rotated, will transport a sensor to the engagement location or to a position where the sensor can be moved to the engagement location. Moreover, the '558 reference fails to disclose or suggest any means for urging a stack of sensors towards a rotatable transport member in a direction substantially perpendicular to a plane containing the axis of rotation of the transport member.

Because the '558 reference fails to disclose or suggest the above-mentioned limitations of claim 21, the '558 reference does not anticipate claim 21.

Independent claim 26 requires, among other things, a transport member that when rotated brings a test strip to an engagement location at which it can be engaged with electrical contacts of a meter. Moreover, claim 26 requires load means provided between the transport member and a housing thereof, for applying a compressive load to a sensor during at least a part of the time when the said sensor is located in the

recessed region of the transport member. The '558 reference fails to disclose or suggest these limitations as is required for a proper anticipation rejection. Thus, because the '558 reference fails to disclose or suggest these limitations of claim 26, the '558 reference fails to anticipate claim 26.

Claim 3 depends from claim 1 and is therefore allowable for the same reasons as claim 1. Additionally, claim 3 requires a sealing means that has a first end that forms a seal around the magazine and that has a second end that locates in a groove in the transport member to form a seal therewith. In contrast, the sealing members 15, 29 of the test devices described and shown in figures 1-4 of the '558 reference engage between the cartridge or magazine 4, 24 that supports the stack of test members 3, 30 and the test members themselves. Moreover the other embodiments of test devices disclosed in figures 5 and 6 of the '558 reference only disclose sealing members 34,46 that engage the cartridge or magazine 32, 42 that supports the stack of test members 31, 43 and a cap or top 33, 45 thereof. Thus, the '558 reference fails to disclose a test device that comprises a sealing means that engages any transport member, as is required by claim 3. Moreover, the '558 reference fails to disclose a test device that comprises a transport member that comprises a groove. As such, the '558 reference cannot possibly disclose a sealing member that has a first end that forms a seal around the magazine and that has a second end that locates in a groove in the transport member to form a seal therewith, as is required by claim 3, and therefore, for these additional reasons, fails to anticipate claim 3.

Claim 4 depends from claims 1 and 3 is therefore allowable for the same reasons as claims 1 and 3. Additionally, claim 4 requires a sealing means which comprises a retractable sleeve which sealingly engages in the groove of the transport member when in an extended configuration and which does not form a seal with the transport member when in a retracted configuration. The '558 reference fails to disclose any retractable sealing means having both an extended configuration and a retracted configuration as recited in claim 4. Thus, for these additional reasons, claim 4 is not anticipated by the '558 reference.

Claim 5 depends from claim 1 and is therefore allowable for the same reasons as claim 1. Additionally, claim 5 requires that a pusher is provided to impart translational motion to a sensor mounted in the said recessed region during and/or after rotation of the transport member so as to bring the sensor to the engagement location. The '558 reference fails to disclose any recessed region of any rotatable transport member. Thus, the '558 reference can not possibly disclose a pusher that imparts any motion on a sensor that is mounted in a recessed region of a rotatable transport member as claimed. Thus, for these additional reasons, claim 5 is not anticipated by the '558 reference.

Claim 6 depends from claims 1 and 5 and is therefore allowable for the same reasons as claims 1 and 5. Additionally, claim 6 requires a pusher that is mounted on the transport member and requires a portion of the pusher to be located in a helical track in the housing whereby rotation of the transport member imparts translational motion to the pusher. As mentioned above, the '558 reference fails to disclose any

pusher mounted on any transport member. Moreover, the '558 reference fails to disclose any helical track in any housing. Thus, the '558 reference can not possibly disclose a pusher that is mounted on the transport member and requires a portion of the pusher to be located in a helical track in the housing whereby rotation of the transport member imparts translational motion to the pusher, as is required by claim 6. For these additional reasons, claim 6 is not anticipated by the '558 reference.

Claims 7 and 8 depend from claim 1 and are therefore allowable for the same reasons as claim 1. Additionally, each of claims 7 and 8 require the sealing means to comprise a seal which is secured in relation to an outer surface of the transport member and which seals the opening of the housing when the transport member is in a specified rotational position. The '558 reverence fails to disclose any seal which is secured in relation to an outer surface of the rotatable transport member and which seals the opening of the housing when any rotatable transport member is in a specified rotational position. For these additional reasons, claims 7 and 8 are each not anticipated by the '558 reference.

Claims 9, 10, and 13 depend from claim 1 and are therefore allowable for the same reasons as claim 1. Additionally, each of claims 9, 10, and 13 require the sealing means to comprise a seal provided on a door which is adapted to fit the said opening so that the moisture tight seal is effected by closure of the door; wherein the door is operatively connected to the transport member so that the door will be open when the transport member is in a first rotational position and closed when the transport member is in a second rotational position. The '558 reference fails to disclose any such door

that is operatively connected to any transport member so that the door will be open when the transport member is in a first rotational position and closed when the transport member is in a second rotational position. For these additional reasons, claims 9, 10, and 13 are each not anticipated by the '558 reference.

Claim 11 depends from claims 1 and 9 and is therefore allowable for the same reasons as claims 1 and 9. Additionally, claim 11 requires the door to be provided with one or more teeth which restrain movement of the stack of sensors against the force of the spring means. The '558 reference fails to disclose any such teeth on any such door. For these additional reasons, claim 11 is not anticipated by the '558 reference.

Claim 12 depends from claims 1, 9, and 11 and is therefore allowable for the same reasons as claims 1, 9, and 11. Additionally, claim 12 requires the transport member to be provided with at least one blade which takes over the function of restraining the stack of sensors when the door is opened. The '558 reference fails to disclose any such blade. For these additional reasons, claim 12 is not anticipated by the '558 reference.

Claim 14 depends from claim 1 and is therefore allowable for the same reasons as claim 1. Additionally, claim 14 requires the transport member to be operationally connected to a return spring which urges the transport member to adopt a specified rotational position at which the sealing means can provide a moisture proof seal between the stack of sensors and the transport member. The '558 reference fails to disclose any such spring which urges the transport member to adopt a specified

rotational position. For these additional reasons, claim 14 is not anticipated by the '558 reference.

Claim 18 depends from claim 17 and is therefore allowable for the same reasons as claim 17. Additionally, claim 18 requires sealing means which make a moisture-proof seal between the transport member and the stack when the transport member is in a specified rotational position. The '558 reference fails to disclose any sealing means which make a moisture-proof seal between any rotatable transport member and the stack. For these additional reasons, claim 18 is not anticipated by the '558 reference.

Claim 20 depends from claim 1 and is therefore allowable for the same reasons as claim 1. Additionally, claim 20 requires the total thickness of the sensor in at least a part of the non-working area is greater than the total thickness of the sensor in the working area. The '558 reference fails to disclose any sensor wherein the total thickness of the sensor in at least a part of the non-working area is greater than the total thickness of the sensor in the working area. For these additional reasons, claim 20 is not anticipated by the '558 reference.

Claim 22 depends from claim 1 and is therefore allowable for the same reasons as claim 1. Additionally, claim 22 requires a load means for applying a compressive load to a sensor during at least a part of the time when the said sensor is located in the recessed region of the transport member. The '558 reference fails to disclose any compressive load on any sensor in any recessed region of any rotatable transport member. For these additional reasons, claim 22 is not anticipated by the '558 reference.

Claim 23 depends from claim 1 and is therefore allowable for the same reasons as claim 1. Additionally, claim 23 requires non-return means which prevent or inhibit transport of a sensor from the engagement location to the magazine and which prevent or inhibit reintroduction of an ejected used sensor to the engagement location. The '558 reference fails to disclose any such non-return means. For these additional reasons, claim 23 is not anticipated by the '558 reference.

Claim 24 depends from claims 1 and 23 and is therefore allowable for the same reasons as claims 1 and 23. Additionally, claim 24 requires the said non-return means and the said load means comprise a single resilient and flexible component. The '558 reference fails to disclose any such single resilient and flexible component. For these additional reasons, claim 24 is not anticipated by the '558 reference.

Claim 25 depends from claim 1 and is therefore allowable for the same reasons as claim 1. Additionally, claim 25 requires ratchet means associated with the stack of sensors which prevent or inhibit movement of the stack in a direction opposite to that in which the spring means urges the stack. The '558 reference fails to disclose any such ratchet means. For these additional reasons, claim 25 is not anticipated by the '558 reference.

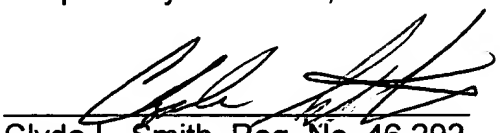
(9) Conclusion

For the reasons set forth above, it is respectfully submitted that Claims 1-27 are allowable over the prior art of International Publication Number WO94/10558, the '558

reference. It is respectfully requested that the rejections of these claims be reversed and the claims allowed.

An oral hearing is not requested.

Respectfully submitted,



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Appendix of Claims on Appeal

1. (Previously Amended) A test device for testing of analyte concentration in a fluid to be applied thereto, the device comprising:

a) a plurality of sensors arranged in a stack, each of said sensors carrying reagent means for producing an electrical signal in response to the concentration of analyte in an applied fluid, each of said sensors having a plurality of electrode tracks for transmitting said electrical signal;

b) a housing having an opening therein and containing the said stack of sensors;

c) electrical contacts mounted in relation to the housing for engaging with electrode tracks on a sensor at an engagement location;

d) a meter connected to the said electrical contacts, having electronics means for producing a signal output which is dependent on the electrical signal from a sensor when the sensor is engaged with the said contacts;

e) a transport member rotatably mounted in the opening of the housing, having an axis of rotation which spans the opening and having an outer surface which is provided with a recessed region adapted to receive a single sensor from the stack;

f) spring means within the housing which urge the stack of sensors towards the transport member and which urge a single sensor into the said recess when the recess is suitably aligned adjacent to the stack;

g) sealing means for making a moisture tight seal between the transport member and the stack when the transport member is in a specified rotational position; and

h) wherein rotation of the transport member with a sensor in the recessed region will transport the sensor to the engagement location or to a position where the sensor can be moved to the engagement location, whereby electrode tracks of the sensor can engage with the said electrical contacts.

2. (Original) A test device as claimed in claim 1, wherein the sensors are stacked in a magazine within the housing, the magazine having a single opening which faces the transport member.

3. (Original) A test device as claimed in claim 2, wherein a first end of the sealing means forms a seal around the magazine and a second end of the sealing means locates in a groove in the transport member to form a seal therewith when the recessed region of the transport member is in register with the stack of sensors.

4. (Original) A test device as claimed in claim 3, wherein the sealing means comprises a retractable sleeve which sealingly engages in the groove of the transport member when in an extended configuration and which does not form a seal with the transport member when in a retracted configuration.

5. (Original) A test device as claimed in claim 1, wherein a pusher is provided to impart translational motion to a sensor mounted in the said recessed region during

and/or after rotation of the transport member so as to bring the sensor to the engagement location.

6. (Original) A test device as claimed in claim 5, wherein the pusher is mounted on the transport member and a portion of the pusher is located in a helical track in the housing whereby rotation of the transport member imparts translational motion to the pusher.

7. (Original) A test device as claimed in claim 1, wherein the said opening is the only opening to the inside of the housing, and wherein the sealing means comprises a seal which is secured in relation to an outer surface of the transport member and which seals the opening of the housing when the transport member is in a specified rotational position.

8. (Original) A test device as claimed in claim 2, wherein the sealing means comprises a seal which is secured in relation to an outer surface of the transport member and which seals the opening of the magazine when the transport member is in a specified rotational position.

9. (Original) A test device as claimed in claim 1, wherein the said opening is the only opening to the inside of the housing, and wherein the sealing means comprises a seal provided on a door which is adapted to fit the said opening so that the moisture

tight seal is effected by closure of the door; wherein the door is operatively connected to the transport member so that the door will be open when the transport member is in a first rotational position and closed when the transport member is in a second rotational position.

10. (Original) A test device as claimed in claim 2, wherein the sealing means comprises a seal provided on a door which is adapted to fit the opening of the magazine so that the moisture tight seal is effected by closure of the door; wherein the door is operatively connected to the transport member so that the door will be open when the transport member is in a first rotational position and closed when the transport member is in a second rotational position.

11. (Original) A test device as claimed in claim 9, wherein the door is provided with one or more teeth which restrain movement of the stack of sensors against the force of the spring means.

12. (Original) A test device as claimed in claim 11, wherein the transport member is provided with at least one blade which takes over the function of restraining the stack of sensors when the door is opened.

13. (Original) A test device as claimed in claim 9, wherein the door is pivotally mounted in relation to the housing.

14. (Original) A test device as claimed in claim 1, wherein the transport member is operationally connected to a return spring which urges the transport member to adopt a specified rotational position at which the sealing means can provide a moisture proof seal between the stack of sensors and the transport member.

15. (Original) A test device as claimed in claim 1, wherein a portion of the sensor to which a fluid sample is to be applied is not supported by the transport member when in the engagement location.

16. (Original) A test device as claimed in claim 1, wherein the transport member has an external profile which is substantially circular in cross section.

17. (Original) A test device for testing of analyte concentration in a fluid to be applied thereto, comprising: a housing containing a stack of test strips and having an opening therein; a transport member rotatably mounted in the opening of the housing, having an axis of rotation which spans the opening; the transport member having a recessed region adapted to receive a single test strip; and spring means which urge the stack towards the transport member; wherein rotation of the transport member with a test strip in the recessed region thereof will bring the said test strip to an engagement location at which it can be engaged with electrical contacts of a meter and at which the test strip will be accessible to permit a user to apply a drop of fluid thereto.

18. (Original) A test device as claimed in claim 17, further including sealing means which make a moisture-proof seal between the transport member and the stack when the transport member is in a specified rotational position.

19. (Original) A test device as claimed in claim 1, wherein each sensor in the or each stack comprises a base member having a working area to which the fluid is to be applied, containing the reagent means, and a non-working area adjacent to the working area, wherein the total thickness of the sensor in at least a portion of the non-working area is at least as great as the total thickness of the sensor in the working area.

20. (Original) A test device as claimed in claim 19, wherein the total thickness of the sensor in at least a part of the non-working area is greater than the total thickness of the sensor in the working area.

21. (Previously Presented) A test device for testing of analyte concentration in a fluid to be applied thereto, the device comprising:

a) a plurality of sensors arranged in a stack, each of said sensors carrying reagent means for producing an electrical signal in response to the concentration of analyte in an applied fluid, each of said sensors having a plurality of electrode tracks for transmitting said electrical signal;

b) a housing having an opening therein and containing the said stack of sensors;

c) electrical contacts mounted in relation to the housing for engaging with electrode tracks on a sensor at an engagement location;

d) a meter connected to the said electrical contacts, having electronics means for producing a signal output which is dependent on the electrical signal from a sensor when the sensor is engaged with the said contacts;

e) a transport member rotatably mounted in the opening of the housing, having an outer surface which is provided with a recessed region adapted to receive a single sensor from the stack;

f) spring means within the housing which urge the stack of sensors towards the transport member in a direction substantially perpendicular to a plane containing the axis of rotation of the transport member, and which urge a single sensor into the said recess when the recess is suitably aligned adjacent to the stack;

g) sealing means for making a moisture tight seal between the transport member and the stack when the transport member is in a specified rotational position; and

h) wherein rotation of the transport member with a sensor in the recessed region will transport the sensor to the engagement location or to a position where the sensor can be moved to the engagement location, whereby electrode tracks of the sensor can engage with the said electrical contacts.

22. (Original) A test device as claimed in claim 1, further including load means for applying a compressive load to a sensor during at least a part of the time when the said sensor is located in the recessed region of the transport member.

23. (Original) A test device as claimed in claim 1, further including non-return means which prevent or inhibit transport of a sensor from the engagement location to the magazine and which prevent or inhibit reintroduction of an ejected used sensor to the engagement location.

24. (Original) A test device as claimed in claim 23, wherein the said non-return means and the said load means comprise a single resilient and flexible component.

25. (Original) A test device as claimed in claim 1, further including ratchet means associated with the stack of sensors which prevent or inhibit movement of the stack in a direction opposite to that in which the spring means urges the stack.

26. (Original) A test device for testing of analyte concentration in a fluid to be applied thereto, comprising: a housing containing a stack of test strips and having an opening therein; a transport member rotatably mounted in the opening of the housing; the transport member having a recessed region adapted to receive a single test strip; and spring means which urge the stack towards the transport member; wherein rotation of the transport member with a test strip in the recessed region thereof will bring the said test strip to an engagement location at which it can be engaged with electrical contacts of a meter and at which the test strip will be accessible to permit a user to apply a drop of fluid thereto or to a position from which the sensor can be moved to the engagement

location; wherein load means are provided between the transport member and a housing thereof, for applying a compressive load to a sensor during at least a part of the time when the said sensor is located in the recessed region of the transport member.

27. (Original) A test device as claimed in claim 1, suitable for use in testing glucose concentration in blood.